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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC L.P.,

Plaintiffs,

vs.

SENORX, INC.,

Defendant.

AND RELATED COUNTERCLAIMS.

Case No. C08 00133 RMW (RS)

DECLARATION OF LYNN J. VERHEY, Ph.D. IN SUPPORT OF PLAINTIFFS' REPLY CLAIM CONSTRUCTION BRIEF (PATENT L.R. 4-5(c))

I, Lynn J. Verhey, Ph.D., declare and state as follows:

1. I make this declaration based on my personal knowledge, training and experience. If called to testify, I could and would testify competently about the subject matter set forth below.

2. I have reviewed defendant SenoRx's Opening Claim Construction Brief, including the declarations and exhibits submitted in support thereof. I submit this declaration to respond to some of the arguments and opinions set forth in those papers. This declaration supplements my May 21, 2008 declaration (dkt. no. 135-7), in which I addressed many of these disputed claim terms. I reserve the right to further address claim construction issues in this case as may be appropriate.

3. I note that in providing his opinions regarding claim construction issues, SenoRx expert Dr. Orton has made both technical arguments and legal arguments based on the patents and their prosecution histories (dkt. no. 132). I submit this declaration primarily to address the technical issues raised by SenoRx and Dr. Orton.

U.S. Patent Nos. 5,913,813 and 6,413,204

I. "Predetermined Constant Spacing" and "Predetermined Spacing"

A. "Predetermined Constant Spacing" ('813 Patent, Claim 1)

4. I understand the Court construed this term previously, and that Hologic requests that the Court adopt its prior construction. I agree with the Court's prior construction.

5. I disagree with SenoRx's proposed construction, which describes the relationship between the inner spatial volume and the radiation transparent wall as exhibiting a "fixed spacing . . . which, for each point on the wall or edge of the inner spatial volume, the distance to the closest point on the outer chamber is the same (i.e. the inner spatial volume and the outer chamber are concentric and the same shape)." In my opinion, this construction does not recognize the realities and limitations of radiotherapy as practiced both in 1997 and today. Brachytherapy balloons and the lumpectomy margins into which they are inserted may be generally spherical in shape, but are never perfect spheres. The same is true of the inner spatial volume. The patent appears to acknowledge that reality by using words such as "substantially" and "generally" when referring to the spacing between the inner spatial volume and the radiation transparent wall. I believe SenoRx's proposed construction conflicts with

these recognized limitations of the claimed apparatus and the related medical procedure by implying that the patent requires exact concentricity and identical shapes.

B. "Predetermined Spacing" ('204 Patent, Claim 3)

6. I understand the Court construed this term previously, and that Hologic requests that the Court adopt its prior construction. I agree with the Court's prior construction.

7. SenoRx cites to my prior declarations (dkt. No. 130 at 8), concluding that based on my prior opinions, I "agree" that "predetermined spacing" means the same thing as "predetermined constant spacing." That is not an accurate representation of my prior declarations. Previously, I stated that by modifying the level of inflation or expansion of the volumes, the spacing "can be" set to a predetermined and constant value. Dkt. No. 130-10 at 10. I also referred to a "constant spacing" when describing the desired shape of the expandable surface element. *Id*. at 9. I disagree with the suggestion that my prior statements and present position conflict. The fact that the spacing between the inner spatial volume and the outer surface can be made substantially constant, or that medical professionals may desire to achieve a constant spacing, does not mean the claim term "predetermined spacing" *requires* a constant spacing.

II. "Three-Dimensional Isodose Profile"

8. I addressed this term in my prior declaration. Dkt. No. 135-7 at 4.

9. I disagree with Dr. Orton's suggestion that a person of ordinary skill in the art would understand that the isodose profile *must be* concentric with the outer expandable surface. Dkt. No. 132 at 16. I also disagree that adding the word "final" to the Court's prior construction clarifies or more accurately defines this claim term. The language is clear as written. If anything, adding the wording creates ambiguity where there is none.

III. "Inner Spatial Volume"

10. I addressed this term, in part, in my prior declaration. Dkt. No. 135-7 at 3-4.

11. I understand that under the Court's prior construction of this term, where the inner spatial volume is a region of space enclosed by a polymeric film wall, the wall does not need to be "distensible." I agree with the Court that the patent imposes no such requirement.

12. One of the invention's objectives is to achieve a "substantially" or "generally" constant spacing between the inner spatial volume and the radiation transparent wall. That objective can be accomplished without the radionuclide being spherical. I disagree with Dr. Orton's conclusions to the contrary. Dkt. No. 132, ¶¶ 23-24. The radioactive sources contemplated in the patent, whether spherical or cylindrical, are very small compared to the typical diameter of a surgical cavity. Thus, no matter the shape, the radionuclides are effectively point sources relative to the diameter of the inflated balloon. That is, whether the nuclide is spherical or non-spherical, the distance to the outer wall is substantially the same.

13. Dr. Orton's discussion of anisotropy (dkt. no. 132 at ¶ 23) does not alter my opinion. While his observations regarding anisotropy are generally true, this discussion is irrelevant to the construction of this claim term. Given the size of the radionuclide relative to the cavity, the radionuclide need not be spherical in shape.

IV. "Means . . . for Rendering Uniform"

14. I understand the Court construed this term previously, and that Hologic requests that the Court adopt its prior construction. I agree with the Court's prior construction.

15. One of ordinary skill in the art would not understand the function of this term as requiring a "substantially" more uniform dose profile, as opposed to merely "more uniform." I see no basis for SenoRx's request to add that requirement.

16. SenoRx also seeks to add the language: "that performs this function by absorbing or attenuating radiation." In my opinion, this construction is unsupported. It adds a limitation that, while perhaps true in some examples or embodiments, is not always true. I agree with Dr. Orton that in some situations, the dose profile can be rendered more or less uniform depending on the particular choice of absorbing or attenuating material. However, in other cases, the dose fall-off will be primarily a function of distance from the radiation source to the tissue. For this additional reason, the language "that performs this function by absorbing or attenuating radiation" would improperly limit the claim.

V. "Inner Closed Chamber"

17. I addressed this term in my prior declaration. Dkt. No. 135-7 at 4. I believe this term means what it says, and that no construction is necessary.

VI. "Providing a Controlled Dose at the Outer Spatial Volume Expandable Surface to Reduce or Prevent Necrosis in Healthy Tissue Proximate to the Expandable Surface"

18. I understand the Court previously construed this term consistent with Hologic's construction. I agree with the Court and Hologic's construction.

19. The term "necrosis" refers to killing cells, not just damaging them. The Court's prior construction more accurately reflects the claim language. In any event, it is impossible to "eliminate the risk of damage" to healthy tissue – as SenoRx and Dr. Orton suggest. (Dkt. No. 132, ¶ 54.) The best one could hope for would be to provide the same dose at the surface of the expandable surface element as at the depth of the target tissue, and this would still not eliminate the risk of damage to healthy tissue.

20. SenoRx also seeks to add the language: "as compared to devices in which the tissue is directly adjacent to the radiation source." I see no basis or need for defining this claim term in comparison to other devices in which the target tissue is adjacent to the radiation source.

U.S. Patent No. 6,482,142

VII. "Apparatus Volume" and "Located So As To Be Spaced Apart from the Apparatus Volume"

A. "Apparatus Volume"

21. I addressed this term in my prior declaration. Dkt. No. 135-7 at 4-5. The apparatus volume, as stated in claim 1 of Patent 142 is the 3-dimensional solid defined by the expandable outer surface and includes both the surface and the volume of space included within that surface.

22.. I disagree with Dr. Orton's statement that Hologic's construction would not provide a person of ordinary skill in the art any guidance as to what is encompassed by the claim term. Dkt. No. 132, ¶ 57.

23. I disagree with Dr. Orton's statement that a person of ordinary skill in the art would understand that the expandable outer surface and the three-dimensional apparatus volume are different.

In my opinion, as a person of ordinary skill in the art, the apparatus volume includes both the expandable surface and the spatial volume defined by that surface.

VIII. "Located So As To Be Spaced Apart from the Apparatus Volume"

24. I addressed this term in my prior declaration. Dkt. No. 135-7 at 5. Since the apparatus volume includes both the expandable surface and the spatial volume defined by that surface, this claim phrase means "located so as to be not on or touching the apparatus volume", in particular the expandable surface which is part of that volume.

IX. ""Asymmetrically Located and Arranged Within the Expandable Surface"

25. I addressed this term in my prior declaration. Dkt. No. 135-7 at 6. I agree with Hologic's construction, which defines the term with reference to the longitudinal axis of the apparatus volume.

X. "Predetermined Asymmetric Isodose Curves"

26. I addressed this term in my prior declaration. Dkt. No. 135-7 at 6. I agree with Hologic's construction. This predetermined asymmetry in the isodose curves is with respect to the longitudinal axis of the apparatus volume.

"Plurality" Claim Terms ('813 and '204 Patents)

XI. "Plurality of Radioactive Solid Particles Placed at Predetermined Locations" and "Plurality of Solid Radiation Sources"

A. "Plurality of Radioactive Solid Particles Placed at Predetermined Locations" ('813 Patent, Claim 12)

27. I agree with Hologic that no construction is necessary. I understand the Court considered a similar claim term in the context of the '204 patent, and concluded that it means what it says. I agree.

28. A person of ordinary skill in the art would understand that the claim in which this term appears teaches emitting therapeutic rays from *more than one location* to achieve "a desired composite

radiation profile." '813 Patent, Claim 12. The irradiation of target tissue from *multiple locations* is the focal point of the claim. One of ordinary skill in the art would also understand that one can achieve a "desired composite radiation profile" by using a single particle or source and moving it to multiple locations, or using multiple particles or sources in predetermined locations. From a dosimetric standpoint, there is no distinction between moving one radionuclide to multiple locations versus the embodiment depicted in Figure 5 of the '813 patent and Figure 4 of the '204 patent.

29. At the time the applications that led to the patents-in-suit were filed, remote afterloaders capable of practicing the multi-core embodiment depicted in Figure 5 of the '813 patent and Figure 4 of the '204 patent did not exist. Remote afterloaders capable of stepping a single radionuclide through multiple dwell points within a brachytherapy balloon applicator, however, were available. Dr. Orton's observations (dkt. no. 132, ¶ 45) regarding the afterloaders available in the early 1990s, in my opinion, undermines his position rather than supporting it. Given the afterloaders available at that time (see e.g., '204 Patent column 4: 54-56), it seems logical that the disputed "plurality" claim language was intended to cover the embodiment where a radionuclide is moved sequentially to multiple locations as well as that of multiple radionuclides at fixed locations. It is important to note that these two embodiments can be used to provide substantially identical dose distributions to the target tissue.

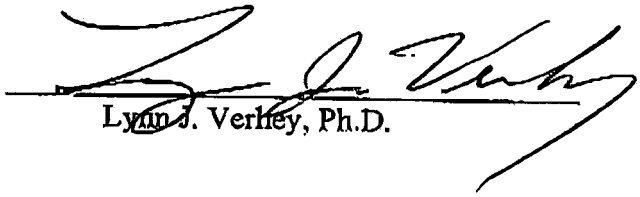
B. "Plurality of Solid Radiation Sources" ('204 Patent, Claim 17)

30. I addressed this term in my prior declaration. Dkt. No. 135-7 at 4, 6. The Court previously considered this term in the context of the '204 patent, and concluded that it requires no construction. I agree.

31. For the same reasons stated above, I believe SenoRx's proposed construction wrongfully limits the definition of this term in a manner that is contrary to the intention of the inventors. The claims focus on performing radiotherapy from multiple locations – hence the reference to a "plurality" of radiation sources. From each location or source, rays are emitted that collectively achieve the desired composite radiation profile. SenoRx's construction would unnecessarily limit the definition of this claim term – and should therefore be rejected.

I declare that the foregoing is true and correct to the best of my knowledge under penalty of perjury.

Executed on May 30, 2008 in San Francisco, California.



Lynn J. Verhey, Ph.D.